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Deborah Charych

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09/06/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/874,091

Applicant(s)

CHARYCH ET AL.

Examiner

My-Chau T. Tran

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 21-52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 6. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment filed 6/20/02 in Paper No. 8 is acknowledged and entered.

Claims 17 and 19 are amended. Claims 1-54 are pending.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I (Claims 1-16 and 53) in Paper No. 8 is acknowledged. However because Claim 17, which is Group II (Claims 17-18), and Claim 19, which is Group III (Claims 19-20) are amended to depend on Claim 1, Groups II and III are now rejoined with Group I. Therefore, Group I is now Claims 1-20 and 53.

The traversal is on the ground(s) that Groups IV (Claim 54), V (Claims 21-36), VI (Claims 37-42), and VII (Claims 43-52) should also be rejoined with Group I (Claims 1-20 and 53) because the search is not burdensome. This is not found persuasive because these inventions are distinct for the reasons given in Paper No. 7 (e.g. each group have different structural format, operations (method steps), or function) and the searches required are not co-extensive thus requiring a burdensome search. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group VI would involve a determination of the patentability of the method step of distributing protein-binding agents from the library into individual storage receptacles while a patentability determination for Group IV would involve a consideration of the patentability of the structural combination of a plurality of different protein-binding agents and a plurality of different antibodies (independent of its use), which are both bound to the substrate. A patentability determination for Group I would involve a determination of the patentability of the structural combination of an anchoring segment bound

Art Unit: 1641

to the surface of the substrate and a linker segment connecting and separating the anchoring and peptidomimetic segment (independent of its use). These considerations are very different in nature.

The requirement is still deemed proper and is therefore made **FINAL**.

3. Claims 21-52 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

4. This application contains claims 21-52 and 54 are drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Drawings***

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "400", "450" and "500" have both been used to designate a process (pg. 27, lines 4 and 12, respectively). The reference characters "412" and "462" have both been used to designate a planar substrate (pg. 27, lines 6 and 14, respectively). The reference characters "422" and "472" have both been used to designate the protein-binding agents (pg. 27, lines 7-8 and 19, respectively). The reference characters "432" and "482" have both been used to designate a blocking agent (pg. 27, lines 9 and 22, respectively). The reference characters "306" (pg. 17, line 14) and "434" (pg. 27, line 8) have both been used to designate the thiol anchoring group. The

Art Unit: 1641

reference characters "506a" and "506b" have both been used to designate labeled samples (pg. 30, lines 6-7). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "434" of figures 4A and 4B (pg. 27, line 8) and "600" of figure 6 (pg. 31, line 4). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "424" of figures 4A and 4B, "A-E" of figure 10, and "200, 202, 204, and 206" of figure 2. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to because it is unclear what these reference characters "410", "420", "430", "460", "470", and "480" are designating. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Specification***

9. The "Attorney Docket No." (see pg. 16, line 15; pg. 24, line 4; pg. 25, line 4) should be replaced with application number and any reference to this application should reflect the change.

Appropriate correction is required.

10. The disclosure is objected to because of the following informalities:

It is unclear whether there are any missing parts from the large blank space on pages 2 and 6.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3, <sup>9,</sup> 16, and 20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 3 recites the limitation "glass, plastic" in line 1. There is insufficient antecedent basis for this limitation in the claim.

b) The acronym "LC" of claims 16 and 20 is not defined in the claim so that those who are ordinary skills in the art would know applicant intended meaning.

c) It is unclear what is meant by the term "amino-modified thiol" of Claim 9.

Art Unit: 1641

d) Claim 20 recites the limitation "avidin-functionalized aminosilane" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4, 6 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Weetall (*Applied Biochemistry and Technology*, 41:157-188, 1993).

Weetall teaches a method and device of immobilizing proteins on an inorganic support through silane coupling (Abstract; pg. 181, lines 16-21; pg. 182, lines 3-34). The proteins of Weetall would incorporate the "peptidomimetic" as defined in the instant specification (pg. 15, lines 1-27). The inorganic support materials consist of either porous or nonporous glasses, silicas, or metal oxides such as  $\text{TiO}_2$  and  $\text{Al}_2\text{O}_3$  (pg. 158, lines 38-42; pg. 159, Table 1 and Table 2). The protein is immobilized to the solid support by a three-step method in which the functional group (anchor) on the solid support is coupled to a linker that would react with the protein (pg. 160, lines 28-38; pg. 166, lines 24-27). The immobilized protein on an inorganic support of Weetall anticipated the claimed "array of protein-binding agent attached to the solid support" of the invention.

Art Unit: 1641

With respect to the kit claim (Claim 53), Weetall anticipated the claimed invention by disclosing the device of immobilized protein on an inorganic support (Abstract; pg. 181, lines 16-21; pg. 182, lines 3-34). The protein is immobilized to the solid support by a three-step method in which the functional group (anchor) on the solid support is coupled to a linker that would react with the protein (pg. 160, lines 28-38; pg. 166, lines 24-27). The immobilized protein on an inorganic support of Weetall anticipated the claimed "array of protein attached to the solid support" of the invention.

15. Claims 1-7, 9-14, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundberg et al. (US Patent 5,624,711).

Sundberg et al. teaches a ligand array of immobilized peptides and other small organic molecules on a variety of derivatized solid substrate (col. 1, lines 64-67 to col.2, lines 1-10; col. 5, lines 66-67 to col. 6, lines 1-2). The peptide of Sundberg would incorporate the "peptidomimetic" as defined in the instant specification (pg. 15, lines 1-27). The solid support can be organic or inorganic (col. 11, lines 20-40). The solid support has functional sites for affixing the derivatization reagent (anchor) (col. 10, lines 34-67). The derivatization reagent has reactive sites for attachment of the linker molecules, which react with the ligand to form a ligand array on a solid support. The ligand includes peptides, proteins, and oligonucleotides (col. 4, lines 43-50; col. 5, lines 36-48). The functional sites on the surface of the support are reactive groups such as amino, thiol, hydroxyl, or siloxane bonds (col. 11, lines 36-48). The groups of reactive sites on the derivatization reagent those are suitable for attachment to a linking molecule include amine, thiol, hydroxyl, amide and ester (col. 11, lines 49-62). The linking molecules



Art Unit: 1641

comprise of hydrocarbon chain or polyoxyethylene (col. 12, lines 47-53). The ligand array of Sundberg anticipated the claimed "array of protein-binding agent attached to the solid support" of the invention.

The features of remaining independent and dependent claims are either specifically described by the reference, or constitute obvious variations in parameters which are routinely modified in the art (e.g. aluminum type of inorganic support of the instant claim 2 and 17, see Sundberg et al. and Chrisey et al., col. 7, lines 21-28; maleimide functional group, see Chrisey et al., col. 8, lines 4-8), and which have not been described as critical to the practice of the invention.

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1641

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 8, 14-16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) in view of Barrett et al (US Patent 5,482,867).

The arrays of immobilized peptides on a solid support of Sundberg et al. are applied for the reasons discussed above.

Sundberg et al. differs from the claimed invention by failing to include biotin as an anchoring group and avidin is coated beneath the anchoring segment.

Barrett et al. teaches an array of immobilized anti-ligands on predefined regions of a surface of a solid support (col. 2, lines 36-41). The method involves attaching to the surface a caged binding member (anchor). The anti-ligand includes peptides (col. 4, lines 34-60). The caged binding member is a photoactivatable biotin analog (col. 5, lines 45-56). Avidin can be immobilized onto the surface of the solid support and bind to biotin (col. 5, lines 57-65). One type of photoactivatable biotin analog is NHS-LC-LC-biotin (col. 14, lines 66-67 to col. 15, lines 1-30).

Art Unit: 1641

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the array of Sundberg et al. by incorporating biotin as an anchoring group and avidin is coated beneath the anchoring segment as taught by Barrett et al. because it would provide the advantage of efficiently and stably attaching a broad range anti-ligands on predefined regions of a solid support (Barrett: col. 2, lines 26-32). Therefore, one would have had reasonable expectation of success of incorporating biotin as an anchoring group and avidin is coated beneath the anchoring segment into the array of Barrett et al. because both Sundberg and Barrett teaches the array of immobilized peptides.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct  
September 5, 2002

*Mary E. Ceperley*  
**MARY E. CEPERLEY**  
**PRIMARY EXAMINER**

*all 1641*